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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,848	01/30/2002	Andrew P. Kloek	12557-002001	9554

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EXAMINER
PAK, YONG D

ART UNIT	PAPER NUMBER
1652	12

DATE MAILED: 08/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,848	KLOEK ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *5-8 and 10-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Claims 1-23 are pending.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-4 and 9) in Paper No. 12 is acknowledged. The traversal is on the ground(s) that Group I should be examined with Group II. Applicants argue that the polypeptides of Group I and II are very similar and thereby examination of both Groups I and II will be more efficient. This is not found persuasive because even though the two polypeptides are from the same source and are similar to each other, their structure is different. The specification defines SEQ ID NO:3 as MDH1 and SEQ ID NO:4 as MDH2 (page 8). Therefore, the polypeptides are patentably distinct for having different substrate specificity and other physical and chemical properties.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-8 and 10-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claim Objections

Claim 9 is objected to as being dependent upon a non-elected base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-3 are drawn to a polypeptide having 70-90% sequence identity with SEQ ID NO:2 with no limitations to the function of the polypeptides. Therefore, this claim is drawn to a large variable genus of polypeptides having unknown activity or inactive variants. Applicants only describe the MDH1 of SEQ ID NO:3 and MDH2 of SEQ ID NO:4. The specification does not describe the function of all the polypeptide sequences derived or modified from SEQ ID NO:3 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. Therefore, applicants fail to describe representative species by identifying characteristics or structural properties other having homology to SEQ ID NO:3.

Claim 9 is drawn to a polypeptide that is 70% identical to SEQ ID NO:3 having MDH (malate dehydrogenase) activity. Even though MDH1 (SEQ ID NO:3) and MDH2 (SEQ ID NO:4) were isolated from *M. incognita* and share greater than 98% homology, the two resulting malate dehydrogenases have different substrate specificity. The

specification does not disclose which amino acids impart a polypeptide as MDH1 or MDH2. Therefore, based on the instant disclosure, it is unpredictable whether a polypeptide is has MDH1 or MDH2 activity.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 1-3 and 9.

Claim 1-3 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the MDH1 of SEQ ID NO:3, does not reasonably provide enablement for polypeptides of unknown function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification teaches how to make and use the MDH1 enzyme of SEQ ID NO:3. However, the function of a polypeptide cannot be predicted from its structure and

the specification does not teach how to use polypeptides with unknown function. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The specification, which places no limitation on the structure of the polypeptides as discussed above, does not support the broad scope of the claims because the specification does **not** establish: (A) regions of the malate dehydrogenase which may be modified without effecting its activity; (B) the general tolerance of to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Therefore, one of ordinary skill would require guidance in order to use variant polypeptides of SEQ ID NO:3 having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, the mere recitation of the name "MDH" is insufficient to convey with clarity that which applicant sees as the invention. Amendment of claim 9 recite the full name of "MDH" can overcome this rejection.

Also in claim 9, the phrase "MDH-like activity" is unclear. Either a polypeptide has MDH activity or it does not have MDH activity.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by www.ss.jircas.affrc.go.jp. The instant claims are drawn to polypeptides having homology to SEQ ID NO:3 and a polypeptide having malate dehydrogenase activity.

The publication of www.ss.jircas.affrc.go.jp teaches a malate dehydrogenase harbored from *Meloidogyne incognita (*page 1 and Figure 1*)*. One of ordinary skill in the art would recognize that the malate dehydrogenase isolated from *M. incognita* is at least 70, 80 or 90% identical to SEQ ID NO:3 since both are isolated from the same source. Therefore, the teaching of www.ss.jircas.affrc.go.jp anticipates claims 1-4 and 9.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

August 18, 2003

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